

Interview Summary

Application No.

09/776,266

Applicant(s)

WOODROW, WAYNE

Examiner

Maury Audet

Art Unit

1654

All participants (applicant, applicant's representative, PTO personnel):

(1) Maury Audet.

(3) _____.

(2) Jay Cinamon, Atty. for Applicant.

(4) _____.

Date of Interview: 13&15 May 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____.

Claim(s) discussed: Elected claims 1-24.

Identification of prior art discussed: WO 95/01185 (now US 5,482,931).

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

* In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: 13 May 2003-Examiner call to Applicant regarding enablement issues surrounding claims. Applicant's specification page 2 describe that WO 95/01185 (now US 5,482,931, Harris et al., Issued January 9, 1996), "Example 5 shows that desmopressin solutions free from preservative lose about half of active principle because of adsorption by the walls of polystyrene, polypropylene and glass tubes, after 24 hours at room temperature." However, this inventions Example 3, Table 1 (page 6), show that the same or nearly the same desmopressin composition in a glass and polymeric container only lost a titre (active principle) of around 2% in 4 days (versus Harris' loss of 50% in 24 hours). Applicant's specification does not indicate how/why the invention, using the same or nearly the same composition without a preservative, was able to overcome the adsorption problems that Harris et al. taught when a preservative was not used.

Based on the discrepancy between the prior art and the present invention, Examiner indicated to Applicant that, without a description as to how the same/nearly the same composition overcame the prior art (Harris et al.), that a section 112 first enablement rejection would form the core of the rejection being sent.

Additionally, the Examiner indicated to Applicant that a preliminary review of Harris et al. ('931) teach a composition, with a peptide (desmopressin)(column 3, line 18-19), with a buffer (citric acid/disodium)(column 3, lines 20-24), an osmolarity agent (NaCl)(column 3, last paragraph), water as a solvent (column 3, line 56); without a preservative (Example 5, column 3, lines 57-61); indicating that at least this reference would likely be used as a 102 (b) reference on Applicant's claims. [Harris et al. teach the use of a buffer, and the other elements above in the invention which appear to be inherently incorporated, absent other evidence, in Example 5, since the focus in Example 5 was how such compositions compared with/without a preservative.].

Examiner noted that the call was made to try to clarify/discuss the issues of enablement, prior to sending the first action. Attorney for Applicant mentioned he would call his client in Italy and try to get back to Examiner within a few days. Examiner indicated that if this was not possible, the action would be sent as discussed and could be dealt with in the response.

15 May 2003-US Attorney for Applicant called to say he was unable to reach the inventors, but had spoken with Applicant's foreign attorney, the latter who stated that European Law may consider "new functionalities" of known compositions as novel. Examiner asked that U.S. Attorney for Applicant pass on to Applicant that such findings may give rise to new methods of use under U.S. practice, but not to the product, if in fact it is found to be known. In closing, Examiner asked that Applicant e-mail inventors to have them point how the composition of Harris et al., namely teaching of desmopressin (with other components) minus the preservative, is distinguishable from the composition claimed in the present invention (and without consideration that they found only about 2% of titer was lost after 4 days, versus Harris et al.'s finding of 50% loss after 24 hours.).

Additionally, Applicant was asked to elect a specific peptide to which the elected claims would be drawn to.

US Attorney stated he would get back to Examiner prior to the mailing of the first action if possible. US Attorney called back on 16 May 2003 to say that the Applicant could not be reached, but that an election of species and clarification of the issues would be done by telephone as soon as Applicant responded to these inquiries.